



FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF MEDICINAL PRODUCTS CLASSIFIED FOR FAST TRACK PROCESSING

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1.0 INTRODUCTION

1.1. SCOPE

This guidelines covers the requirement and processing of all allopathic drugs classified by the FDA for expedited processing for registration. Currently, the following categories of applications are covered;

- World Health Organization (WHO) Prequalified Products
- Public health products (Anti-Retroviral Drugs, Anti-Malaria drugs, Drugs for Tuberculosis, Reproductive health products and Drugs for neglected health products).
- Product Registered by countries within the International Conference on Harmonization (ICH) region

2.0 GLOSSARY

In the context of this guideline, the following words/phrases are defined as follows:

Allopathic drug: Any product or substance other than a medical device, which is to be administered to one or more human beings or animals on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose.

Medicinal purpose: means treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

Applicant: The product owner or licence holder. Representatives of licence holders

Drug, medicine or pharmaceutical product: means a substance or mixture of substances prepared, sold or represented for use in -

- (a) Diagnosis, treatment, mitigation or prevention of disease, disorders or abnormal physical state or the symptoms of it in man or animal
- (b) Restoring, correcting or modifying organic functions in man or animal.

Finished Pharmaceutical Product (FPP): A product that has undergone all stages of production, including packaging in its final container and labelling.

Manufacture (manufacturing): Means all operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

Manufacturer: Means a person or firm that is engaged in the manufacture of product(s).

Variation: Means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

3.0 REQUIREMENTS

3.1 WHO PREQUALIFIED MEDICINAL PRODUCTS

- This guideline outlines the procedure for the application and registration of WHO prequalified allopathic drugs by the Food and Drugs Authority (FDA).
- This is based on a collaborative procedure between the WHO Prequalification of Medicines Programme (WHO/PQP) and the FDA in the assessment and accelerated registration of WHO prequalified allopathic drugs.
- Applicants with allopathic drugs that have been prequalified by the WHO/PQP can take advantage of this procedure for fast track registration of their prequalified medicinal product by the FDA.

3.1.1 APPLICATION STEPS

1. Applicant should submit the product dossier for a WHO-prequalified pharmaceutical product to the Food and Drugs Authority (FDA). The dossier submitted to the FDA should be the same as submitted to the WHO-PQP during the initial prequalification procedure, and subsequent variation documentation where applicable; The application should include;
 - a) A completed application form for the registration of allopathic drug by the FDA, including the same technical information as that submitted to WHO/PQP. The technical part of the dossier should be identical to the current version of the WHO/PQP dossier.
 - b) The following country specific documentation;
 - i) Executed batch manufacturing records of one production batch.
 - ii) Where applicable, long-term stability studies protocol and report conducted at Zone IVB conditions
 - iii) Copy of the current version of Quality Information Summary (QIS) submitted to the WHO.

- c) Pay the required application fees for the registration of allopathic drugs as per the fee schedule of the FDA. (access a copy of the fee schedule at www.fdaghana.gov.gh)
2. In situations where the applicant wishes to apply the Procedure to an application which is already pending with FDA, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to WHO.
3. Complete and submit an expression of interest form (Part A of Appendix 3) to the FDA through the WHO-PQ collaborative procedure focal person of the FDA.
4. The FDA shall communicate its consent to apply the procedure to the application for registration of the product and to request the WHO-PQ to share productspecific information by completing and signing Part B of Appendix 3.
5. Applicant shall then complete and submit an expression of interest form (Part A of Appendix 3) to WHO-PQP directing the PQP to provide full access to the information on the prequalified product to the FDA.

3.1.2 PROCESSING

The FDA shall process the application and communicate its decision on the product to the applicant and WHO within 90 calendar days.

3.1.3 POST APPROVAL

All post-prequalification variations submitted to WHO shall be submitted simultaneously to the FDA after the product has been registered by the FDA.

3.2 PROGRAM DRUGS

Medicinal product that are listed under any of the following Ministry of Health Programs shall be classified as fast track applications;

- i. Anti-Retroviral Drugs
- ii. Anti-Malaria drugs
- iii. Drugs for Tuberculosis
- iv. Reproductive health products
- v. Drugs for neglected tropical diseases

3.2.1 APPLICATION STEPS

Applicant for the registration of allopathic drug under this category shall:

1. Submit full application as per the FDA's requirement for the registration of allopathic drug.
2. Pay the required application fees for the registration of allopathic drugs as per the fee schedule of the FDA. (access a copy of the fee schedule at www.fdaghana.gov.gh).
3. Submit the required number of samples of the product as per the FDA's sample schedule.

3.2.2 PROCESSING

The FDA shall process the application and communicate its decision on the product to the applicant within 90 calendar days.

3.3 SRA REGISTERED DRUGS

Medicinal products applications with valid marketing authorization from a country or region considered by the FDA as stringent. This will include countries that were members of the ICH prior to 2015.

3.3.1 APPLICATION STEPS

Applicant for the registration of allopathic drug under this category shall:

1. Submit full application as per the FDA's requirement for the registration of allopathic drug.
2. Pay the required application fees for the registration of allopathic drugs as per the fee schedule of the FDA. (access a copy of the fee schedule at www.fdaghana.gov.gh).
3. Submit the required number of samples of the product as per the FDA's sample schedule.

3.3.2 PROCESSING

The FDA shall process the application and communicate its decision on the product to the applicant within 90 calendar days.